Italian Medicines Agency

Report No: ***IT/NCR/API/2/2015***

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer [1]

Part 1

Issued following an inspection in accordance with :
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:
The manufacturer: ***PARABOLIC DRUGS LIMITED***
Site address: ***PDL-2, Plot No. 45, Industrial Area, Phase II, Panchkula District, Haryana, 134 113, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-06-17*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC .

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

1 NON-COMPLIANT MANUFACTURING OPERATIONS

Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

1.4	Other products or manufacturing activity
	1.4.1 Manufacture of 1.4.1.4 Other: Active Substances(en)

Manufacture of active substance. Names of substances subject to non-compliant :
DICLOXACILLINA SODICA(it) / DICLOXACILLIN SODIUM(en)

Part 3

1. Nature of non-compliance:

The quality management system was found to be seriously uncontrolled and deficient in all “Principles” (except principle 2.13 and 2.14) reported in the EU- GMP requirements as evidenced by critical and major deviations found in the following areas: inadequate storage and control of documents and samples and material, falsification of documents and data, integrity and security of data in the QC laboratory, Change Control, Deviations management and Risk management. In total 27 deficiencies were found: 3 classified as Critical were found in the area of Documentation management system, Falsification and Security and integrity data; 7 classified as Major deficiencies were found in the area of QC, Personnel, Documentation and Change Control.

Action taken/proposed by the NCA

Recall of batches already released
Each involved NCA should evaluate, following assessment conducted in conjunction with MAHs, if a recall of medicinal product is needed. Evaluation should take into account if there are alternative suppliers and potential risk of shortage. Given the nature of non-compliances, assessment should include a complete retest of all imported batches of active substance.

Prohibition of supply
Due to the nature of non compliances, prohibition of supply is recommended.

Suspension or voiding of CEP (action to be taken by EDQM)
Withdrawal of all CEPs is ongoing.

Others
This supplier should not be approved in any new / ongoing applications. Each involved NCA should evaluate if the supplier should be removed from existing MAs.

Additional comments
This inspection was performed in the framework of the CEP dossier for the manufacture of Dicloxacillin sodium. The found deficiencies could affect the other penicillin family APIs manufactured at the site (AMOXICILLIN TRIHYDRATE, PIVAMPICILLIN,FLUCLOXACILLIN SODIUM,CLOXACILLIN SODIUM, AMPICILLIN TRIHYDRATE, AMPICILLIN ANHYDROUS,BACAMPICILLIN HYDROCHLORIDE).

2015-07-28

Name and signature of the authorised person of the Competent Authority of Italy

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